DEC - 8 2000

K002691

Com-Med International, Inc.

2625 Butterfield Road
Oakbrook, Illinois 60523
630-368-3928
Fax: 630-368-3929

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
COM-MED O.R. TOWELS

Manufacturer:	Com-Med International, Inc. 2625 Butterfield Road Suite 138S Oakbrook, Illinois 60523
Regulatory Affairs Contact:	Michele Vovolka Vantage Consulting International, Ltd. P.O. Box 848 Grayslake, Illinois 60030
Telephone:	(847) 856-0355
Date Summary Prepared:	October, 2000
Product Trade Name:	Com-Med O.R. Towels
Common Name:	Surgical Towel
Classification:	Class II per 21 CFR §878.4370
Predicate Devices:	Broadline O.R. Towels A Plus International O.R. Towels
Description:	The Com-Med O.R. Towels are made of 100% cotton that have been pre-washed and delinted. The towels are available in blue, green and white.
Intended Use:	This is a single use disposable surgical towel intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The O.R. Towel is further used as a fluid absorbing towel during surgery or as a device to dry hands of the O.R. personnel.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
COM-MED O.R. TOWELS

Substantial Equivalence: The Com-Med O.R. Towels are substantially equivalent to the Broadline O.R. Towels and A Plus O.R. Towels in that they provide the following characteristics:

- intended use is the same
- size, configuration, color are similar
- made of 100% cotton
- physical properties are similar

Summary of Testing: All materials used in the fabrication of this Com-Med O.R. Towels were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization and irritation/intracutaneous reactivity. These materials also were tested in accordance with industry recognized test methods including absorptive capacity, absorption capacity, flammability and tear resistance. The Com-Med OR Towels were found to be acceptable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Com-Med International, Incorporated
C/O Ms. Michele Vovolka
Vantage Consulting International, Limited
P.O. Box 848
Grayslake, Illinois 60030

Re: K002691
Trade Name: Com-Med O.R. Towel - Non-Sterile, Blue, Green, White
Regulatory Class: II
Product Code: KKX
Dated: October 27, 2000
Received: October 30, 2000

Dear Ms. Vovolka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

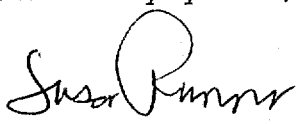
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for Timothy A. Ulatowski
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Com-Med International
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Suite 1385
Oak Brook, Illinois 60523 USA

630-368-3928
FAX: 630-368-3929

510(k) Number (if known): K002691

Device Name: Com-Med O.R. Towel

Indications For Use: This is a single use disposable surgical towel intended to be used a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The O.R. towel is also to be used for the absorption of fluids, including blood and body fluids or as a general use towel for drying hands.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K 002691